

PMA Monthly approvals from 10/1/2019 to 10/31/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190011	10/18/2019	PMAO - PMA Origir	LIAISON XL MUREX HCV AB; LIAISON XL MUREX CONTROL HCV AB	DIASORIN INC.	<p>Approval for the LIAISON XL MUREX HCV Ab. The LIAISON XL MUREX HCV Ab is an in vitro chemiluminescent immunoassay for the qualitative determination of specific antibodies to hepatitis C virus (anti-HCV) in human adult and pediatric serum and plasma (lithium and sodium heparin, sodium citrate and potassium EDTA) samples including separator tubes, on the LIAISON XL Analyzer. It is intended to be used as an aid in the diagnosis of HCV infection. The assay may also be used as an aid in the diagnosis of HCV infection in pediatric subjects and in pregnant women. The test does not determine the state of infection or associated disease.</p> <p>The assay is not intended for use in screening blood, plasma, or tissue donors.</p> <p>The LIAISON XL MUREX Control HCV Ab (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL Murex HCV AB assay. The performance characteristics of LIAISON Controls have not been established for any other assays or instrument platforms different from LIAISON XL.</p>
P190014	10/23/2019	PMAO - PMA Origir	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	<p>Approval of Myriad myChoice® CDx. Myriad myChoice® CDx is a next generation sequencing-based in vitro diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status for treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling.</p> <p>Table1---Tumor Type: Ovarian Cancer, Biomarker: Myriad HRD (defined as deleterious or suspected deleterious mutations in BRCA1 and BRCA2 genes and/or positive Genomic Instability Score), Therapy: Zejula® (niraparib)</p>

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S063	10/24/2019	R - Real-Time Proc	SURGICEL ABSORBABLE HEMOSTATS	ETHICON, INC.	Approval for packaging changes related to the automated process change from manual to automated foiling and cartoning at the Ethicon SARL, Neuchatel Switzerland site. In addition, Ethicon will harmonize SURGICEL NU-KNIT and SURGICEL® Original packaging components.
N970003/S242	10/18/2019	R - Real-Time Proc	PACEMAKER DEVICES: ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, AND PROPONENT	BOSTON SCIENTIFIC CORP.	Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application.
P790005/S065	10/24/2019	Y - 135 Review Tra	OSTEOSTIM(R)	EBI, LLC	Approval to qualify and place into service an upgraded and redesigned Reverse Osmosis, Deionized (RO/DI) Water System along with its ancillary equipment and components at Zimmer Biomet, EBI Patient Care, Guaynabo, Puerto Rico Manufacturing and Distribution Facility.
P840001/S445	10/23/2019	S - Special CBE	RESTORE, ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULAITON LEADS	MEDTRONIC NEUROMODULATION	Approval for labeling changes to update existing Notes to Cautions and minor editorial changes for clarification and cross-therapy alignment purposes to the labeling for the; Spinal Cord Stimulation (SCS) Leads 1x8 Family, Injex Anchor Accessory Kits, Intellis Implantable Neurostimulation System for SCS, and SCS Screening Trial Leads.
P850035/S054	10/24/2019	Y - 135 Review Tra	EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR	EBI, LLC	Approval to qualify and place into service an upgraded and redesigned Reverse Osmosis, Deionized (RO/DI) Water System along with its ancillary equipment and components at Zimmer Biomet, EBI Patient Care, Guaynabo, Puerto Rico Manufacturing and Distribution Facility.
P850068/S013	10/10/2019	R - Real-Time Proc	SILSOFT (ELASTOFILCON A) CONTACT LENSES	BAUSCH & LOMB, INC.	Approval to remove the prismatic error test method and acceptance criteria from the finished product specifications.
P850079/S081	10/25/2019	Y - 135 Review Tra	HYDRASOFT (METHAFILCON B) CONTACT LENS	COOPERVISION, INC.	Approval for the use of autoclave Getinge C to provide back up autoclave capacity for lathing produced products in the MTO (Made to Order) Business Unit at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P860004/S330	10/16/2019	Y - 135 Review Tra	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for the manufacturing change of the bi-wing anchor from transfer molding technology to liquid injection molding technology.
P860004/S336	10/08/2019	Y - 135 Review Tra	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for manufacturing changes and final quality control inspection methods to a device component of the SynchroMed II Infusion System, Ascenda Intrathecal Catheters.
P880086/S299	10/18/2019	N - Normal 180 Day	ACCENT, IDENTITY,	ST. JUDE	Approval for an alternate pre-molded header and a sterile barrier inner package tray

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P890003/S418	10/01/2019	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for the Model 5242 Integrated Diagnostics Data Calculation Module to enable alert notifications.
P910077/S173	10/18/2019	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval to modify the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application.
P920046/S011	10/09/2019	O - Normal 180 Day	FILSHIE CLIP (MARK VI) SYSTEM	FEMCARE LTD.	Approval for a manufacturing site change for the Filshie Clip System Classic Applicator.
P950037/S204	10/04/2019	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for programmer software version 1902.U.
P960013/S108	10/25/2019	Y - 135 Review Tra	TENDRIL ST/STS STEROID ELUTING CARDIAC LEADS	ST JUDE MEDICAL	Approval to update the in vitro elution methods.
P960040/S441	10/18/2019	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application.
P970004/S300	10/10/2019	S - Special CBE	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval to modify the Verify External Neurostimulator User Manual by 1) adding a warning regarding making connections outside the sterile field; and 2) adding a caution regarding battery depletion and replacement.
P980006/S029	10/10/2019	R - Real-Time Proc	PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR	BAUSCH & LOMB, INC.	Approval to remove the prismatic error test method and acceptance criteria from the finished product specifications.
P980023/S094	10/04/2019	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for programmer software version PSW 1902.U.
P980035/S601	10/01/2019	O - Normal 180 Day	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for labeling updates.
P980040/S098	10/01/2019	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for an additional packaging configuration for TECNIS®, TECNIS® OptiBlue, TECNIS® Multifocal, TECNIS® Toric, TECNIS® Symphony and TECNIS® Symphony Toric one-piece IOLs into the new Simplicity Delivery System.

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P980040/S103	10/23/2019	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for modification of the manufacturing resulting in squared and frosted haptics.
P990004/S036	10/30/2019	S - Special CBE	SURGIFOAM ABSORBABLE GELATIN SPONGE, U.S.P.	FERROSAN MEDICAL DEVICES A/S	Approval for an update to the labeling within the Adverse Events section to strengthen information on adverse reactions related to unapproved uses for catheter embolization.
P000009/S081	10/04/2019	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for programmer software version PSW 1902.U.
P000025/S113	10/15/2019	O - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval of the Single-Sided Deafness and Asymmetric Hearing Loss Post-Approval Study protocol.
P010012/S508	10/18/2019	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUIITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILL	BOSTON SCIENTIFIC CORP.	Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application.
P010030/S124	10/11/2019	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for an alternate Velcro Loop Fastener on the LifeVest Wearable Defibrillator.
P020004/S164	10/02/2019	Y - 135 Review Tra	EXCLUDER BIFURCATED ENDOPROTHESIS	W.L. GORE & ASSOCIATES, INC	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P020050/S033	10/03/2019	R - Real-Time Proc	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for a minor design change (software bugfix) to the WaveLight® EX500 Laser System and the associated WaveNet Planning Software (WPS).
P030005/S188	10/18/2019	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application.
P030008/S029	10/03/2019	R - Real-Time Proc	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for a minor design change (software bugfix) to the WaveLight® EX500 Laser System and the associated WaveNet Planning Software (WPS).
P030017/S328	10/20/2019	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for minor design changes to the IPG Header in the Precision Spectra, Spectra WaveWriter, Precision Novi, Precision Montage and Precision Montage MRI Spinal Cord Stimulator (SCS) Systems.

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P040002/S062	10/08/2019	R - Real-Time Proc	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, INC.	Approval for a shelf-life extension for the AFX2 device system.
P040024/S116	10/08/2019	R - Real-Time Proc	RESTITLANE INJECTABLE GEL	Q-MED AB	Approval for reclassification of Impurity C in Lidocaine (HCl) of RESTYLANE Injectable Gels from a Specified Unidentified Impurity to an Unspecified Unidentified Impurity.
P040027/S072	10/02/2019	Y - 135 Review Tra	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P040029/S009	10/24/2019	N - Normal 180 Day	EUCLID SYSTEMS ORTHOKERATOLOGY (TISILFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Approval for the addition of an alternate lens blank supplier, with a change to the contact angle specification, for the manufacture of the Euclid Systems Orthokeratology (tisilfocon A) Contact Lenses for Overnight Wear.
P040037/S130	10/02/2019	Y - 135 Review Tra	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P040037/S133	10/15/2019	R - Real-Time Proc	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Approval a modification to a tolerance value within the device design specification
P040043/S110	10/02/2019	Y - 135 Review Tra	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P050006/S075	10/02/2019	Y - 135 Review Tra	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES, INC	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P050023/S134	10/04/2019	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STERIOD LV PACING LEAD	BIOTRONIK, INC.	Approval for programmer software version PSW 1902.U.
P050050/S012	10/21/2019	R - Real-Time Proc	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATION	Approval for a change in sealing to the packaging for the existing STAR implants.
P070008/S106	10/04/2019	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for programmer software version PSW 1902.U.
P070008/S107	10/04/2019	O - Normal 180 Day	COROX OTW BP	BIOTRONIK, INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P070026/S061	10/27/2019	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for a manufacturing site located at for a manufacturing site located at Synergy Health Westport Ltd., Lodge Road, Westport Mayo, Ireland for the for terminal gamma irradiation sterilization of the Summit Hip Stems

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P070026/S062	10/27/2019	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDI CS, INC.	Approval for a manufacturing site located at Synergy Health Reading Ltd. Marcus Close Thilehurst, Reading, Bershire, UK for the for terminal gamma irradiation sterilization of the Summit Hip Stems.
P080003/S008	10/24/2019	N - Normal 180 Day	SELENIA DIMENSIONS FULL FIELD DIGITAL MAMMOGRAPHY SYSTEM	HOLOGIC, INC.	Approval for software option 3DQuorum™ technology, which generates thicker 6 mm slices (also referred as SmartSlices or slabs) and change to the indications for use statement as a result of this update.
P080004/S023	10/25/2019	Y - 135 Review Tra	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for an alternate supplier for the PSC24 preset tips and to use a new mold.
P080011/S087	10/25/2019	Y - 135 Review Tra	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Approval for the use of autoclave Getinge C to provide back up autoclave capacity for lathing produced products in the MTO (Made to Order) Business Unit at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080012/S062	10/22/2019	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM, PUMP FIRMWARE PATCH 0.28	FLOWONIX MEDICAL, INC.	Approval for introducing Software Version 0.28 for the Prometra II Pumps (REF 13827, 20 mL Pump and Ref 16827, 40 mL Pump).
P080020/S035	10/30/2019	R - Real-Time Proc	GEL-ONE	SEIKAGAKU CORP.	Approval for a change to the design of the Finger Grip of the Gel-One container closure system.
P080025/S195	10/10/2019	S - Special CBE	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODU LATION	Approval to modify the Verify External Neurostimulator User Manual by 1) adding a warning regarding making connections outside the sterile field; and 2) adding a caution regarding battery depletion and replacement.
P100047/S139	10/21/2019	O - Normal 180 Day	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval for revisions to the Instructions for Use to include findings from the Bridge-to-Transplant PAS03 study and data from longer term follow-up of ENDURANCE Supplemental study subjects.
P110013/S095	10/17/2019	Y - 135 Review Tra	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval to automated the stent pre-clean manufacturing processes for the Resolute Integrity and Resolute Onyx Drug Eluting Stents.
P110013/S096	10/22/2019	Y - 135 Review Tra	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for implementing the option of a reusable polypropylene sterilization tote for the transportation of the product to the contract sterilization supplier, during sterilization and return from the contract sterilization supplier.
P110013/S098	10/17/2019	R - Real-Time Proc	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for introducing changes to the material of the desiccant (molecular sieve material) added to the product packaging post sterilization of the Resolute Integrity product.

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P110016/S064	10/09/2019	S - Special CBE	FLEXABILITY ABLATION CATHETER AND FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for the addition of a warning statement to the instructions for use regarding atrioesophageal fistulas.
P110033/S040	10/22/2019	N - Normal 180 Day	JUVEDERM VOLUMA XC	ALLERGAN	Approval for the use of an additional supplier of hyaluronic acid raw material in the manufacture of Juvéderm Voluma XC, Vollure XC and Volbella XC.
P130005/S027	10/09/2019	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for changes to the Orbital Atherectomy Device Component for the Coronary Classic Crown Diamondback 360 Coronary OAS.
P130006/S069	10/02/2019	Y - 135 Review Tra	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P130006/S072	10/15/2019	R - Real-Time Proc	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Approval for a modification to a tolerance value within the device design specification.
P130013/S033	10/18/2019	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval to update the clinical data in the directions for use with the currently available data and make minor changes to the language in the directions for use and patient brochure.
P130022/S021	10/15/2019	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for changes made to MRI Guidelines Manual for the Senza System by adding a new MRI claim for IPG1000/1500/2000.
P130022/S026	10/25/2019	R - Real-Time Proc	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval to make changes to the software for the Clinical Programmer, model CLPG2000/CLPG2500 upgrading the software from version 1.7 to 2.0.
P130026/S051	10/09/2019	S - Special CBE	TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL	Approval for the addition of a warning statement to the instructions for use regarding atrioesophageal fistulas.
P130026/S053	10/22/2019	S - Special CBE	TACTICATH QUARTZ CATHETER CONTACT FORCE ABLATION CATHETER	ST. JUDE MEDICAL	Approval for manufacturing modifications to sulfuric acid immersion times for the TactiCath Quartz Contact Force Ablation Catheter
P140019/S003	10/11/2019	O - Normal 180 Day	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Approval for an updated package insert that incorporates the 24-month follow-up data from all subjects enrolled in the original clinical study.

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P140032/S036	10/02/2019	R - Real-Time Proc	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for a shelf life extension of the Model 845PAH Catheter Patency Kit shelf life from 24 months to 48 months.
P140033/S031	10/18/2019	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for an alternate pre-molded header and a sterile barrier inner package tray modification.
P150012/S081	10/18/2019	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application.
P150021/S039	10/07/2019	Y - 135 Review Tra	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for an alternate supplier for the PCB of the reader component of the FreeStyle Libre, FreeStyle Libre 14-day, and FreeStyle Libre Pro Flash Continuous Glucose Monitoring Systems.
P150031/S021	10/20/2019	R - Real-Time Proc	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for minor design changes to the IPG Header in the Vercise PC and Vercise Gevia Deep Brain Stimulation (DBS) systems.
P150034/S008	10/09/2019	O - Normal 180 Day	RAINDROP NEAR VISION INLAY	RVO 2.0, INC. (D.B.A. OPTICS MEDICAL)	Approval to temporarily suspend the New Enrollment PAS due to not distributing or marketing of the device.
P160001/S033	10/18/2019	O - Normal 180 Day	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for the revised protocol for the post-approval study (PAS) protocol.
P160004/S027	10/02/2019	Y - 135 Review Tra	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.
P160014/S011	10/15/2019	R - Real-Time Proc	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for changes to the polycarbonate resin used in the luer component of the delivery system.
P160021/S020	10/02/2019	Y - 135 Review Tra	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology.

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P160026/S010	10/25/2019	N - Normal 180 Day	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/MONITOR, LIFEPAK 20E DEFIBRILLATOR/MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/MONITOR	PHYSIO-CONTROL. INC.	Approval for minor design changes to several Printed Circuit Board Assemblies (PCBA) and a printer assembly component.
P160030/S030	10/07/2019	Y - 135 Review Tra	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for an alternate supplier for the PCB of the reader component of the FreeStyle Libre, FreeStyle Libre 14-day, and FreeStyle Libre Pro Flash Continuous Glucose Monitoring Systems.
P160031/S002	10/25/2019	N - Normal 180 Day	ASPIRE CRISTALLE DIGITAL BREAST TOMOSYNTHESIS OPTION	FUJIFILM MEDICAL SYSTEMS U.S.A., INC.	Approval for changing the image processing in DBT reconstruction to Iterative Super-Resolution Reconstruction (ISR) and applying new image processing, Dynamic Visualization II for mammography (DVIIm), to the DBT and the FFDM images.
P160043/S024	10/17/2019	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval to automated the stent pre-clean manufacturing processes for the Resolute Integrity and Resolute Onyx Drug Eluting Stents.
P160043/S025	10/22/2019	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for implementing the option of a reusable polypropylene sterilization tote for the transportation of the product to the contract sterilization supplier, during sterilization and return from the contract sterilization supplier.
P160048/S014	10/29/2019	O - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for a manufacturing site located at Steris Isomedix Services, 3459 South Clinton Ave., South Plainfield, NJ 07080 for use as a sterilization site for the sensor insertion tools of the Eversense Continuous Glucose Monitoring System.
P160049/S004	10/11/2019	N - Normal 180 Day	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for 150 mm and 200 mm balloon lengths for the Stellarex 0.035 OTW Drug-coated Angioplasty Balloon.
P160052/S001	10/11/2019	O - Normal 180 Day	PARTOSURE TEST	QIAGEN INC	Approval of the revised protocol for the post-approval study (PAS) protocol
P170002/S005	10/29/2019	R - Real-Time Proc	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for extension of products' shelf-life from 17 months to 36 months.
P170003/S007	10/04/2019	O - Normal 180 Day	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for updates to the Instructions for Use for the Lutonix 035 Model 9010 to reflect the 24-month data from the AV IDE Cohort Post-Approval Study.
P170003/S012	10/02/2019	S - Special CBE	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval for updates to the device labeling to communicate safety information regarding paclitaxel-coated devices for treatment of femoropopliteal arterial disease.

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P170018/S004	10/23/2019	R - Real-Time Proc	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for a labeling change to support a different configuration of the LIFEPAK CR2 defibrillator.
P170019/S007	10/11/2019	R - Real-Time Proc	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for implementation of FoundationOne CDx (F1CDx) QSR pipeline v3.2.0.
P170032/S002	10/01/2019	O - Normal 180 Day	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	SEQUENT MEDICAL, INC	Approval for a manufacturing site located at MicroVention Inc. 35 Enterprise, Aliso Viejo, California, for the Woven EndoBridge (WEB) Aneurysm Embolization System.
P170034/S001	10/08/2019	O - Normal 180 Day	HYDRUS MICROSTENT	IVANTIS, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170035/S005	10/10/2019	R - Real-Time Proc	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Approval to remove the prismatic error test method and acceptance criteria from the finished product specifications.
P170039/S002	10/03/2019	O - Normal 180 Day	CUSTOMFLEX ARTIFICIAL IRIS	CLINICAL RESEARCH CONSULTANTS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P170042/S003	10/31/2019	O - Normal 180 Day	COVERA ₂ VASCULAR COVERED STENT	C.R. BARD, INC	Approval of the protocols for the post-approval studies (PAS) protocol.
P180001/S001	10/31/2019	O - Normal 180 Day	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Approval of the charter for the surveillance project.
P180002/S009	10/02/2019	O - Normal 180 Day	ZEPHYR VALVE REGISTRY (ZEVr)	PULMONX CORPORATION	Approval for the enrollment of at least 20 patients with the new sized Zephyr valve (5.5 LP EBV).
P180014/S001	10/29/2019	O - Normal 180 Day	XPS ₂ WITH STEEN SOLUTION ₂ PERFUSATE	XVIVO PERFUSION, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P180029/S008	10/30/2019	R - Real-Time Proc	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for replacement of the current luer-activated valve component on the LOTUS Edge delivery system.
P180036/S003	10/23/2019	N - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for the 2-lead OPTIMIZER Smart Cardiac Contractility Modulation System.

Total: 100

30-Day Notice

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N12159/S064	10/08/2019	X - 30-Day Notice	SURGICEL ORIGINAL ABSORBABLE HEMOSTAT	ETHICON, INC.	Mechanical and system upgrades on the automated Foiling Line G11719 for the inspection of hermetically sealed SURGICEL original foil pouches to add cameras to image the bottom of the foil pouch and a modification of the vision conveyor to accommodate the added cameras.
N12159/S065	10/30/2019	X - 30-Day Notice	SURGICEL POWDER	ETHICON, INC.	Change in the sampling plan utilized in the manufacturing process of SURGICEL Powder.
N970003/S244	10/29/2019	X - 30-Day Notice	NON-MRI PACEMAKERS	BOSTON SCIENTIFIC CORP.	Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method.
P840001/S444	10/13/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components.
P840001/S446	10/24/2019	X - 30-Day Notice	RESTORE, ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update several manufacturing process changes for the XT097 and XT116 TAZ Series tantalum capacitors.
P850007/S043	10/08/2019	X - 30-Day Notice	PHYSIOSTIM AND SPINALSTIM	ORTHOFIX, INC.	Modify the manufacturing process for sewing the garment assembly for the Orthofix SpinalStim Model 5212 and modify the manufacturing process to cut, split, and strip the ribbon cable for the Orthofix CervicalStim Model 5505 and Orthofix PhysioStim Models 53XX.
P860004/S342	10/01/2019	X - 30-Day Notice	SYNCHROMED (SM) INFUSION SYSTEM	MEDTRONIC INC.	Alternate receiving inspection site to perform incoming inspection activities of the SynchroMed II pump tubing for tensile strength and elongation.
P860004/S343	10/13/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components.
P860004/S344	10/24/2019	X - 30-Day Notice	SYNCHROMED INFUSION	MEDTRONIC	Update several manufacturing process changes for the XT097 and XT116 TAZ Series

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P860057/S192	10/28/2019	X - 30-Day Notice	PERIMOUNT BIOPROSTHESIS, PERIMOUNT MAGNA AORTIC BIOPROSTHESIS, PERIMOUNT MAGNA EASE BIOPROSTHESIS, AND PERIMOUNT PLUS BIOPROSTHESIS	EDWARDS LIFESCIENCE S, LLC.	Modifications to the final assembly cleanroom and the associated gowning room.
P910001/S110	10/21/2019	X - 30-Day Notice	CVX-3000 EXCIMER LASERT SYSTEM AND ELCA CORONARY ATHERECTOMY CATHETERS	SPECTRANETI CS CORP.	Implement additional fiber production equipment.
P910023/S419	10/15/2019	X - 30-Day Notice	ELLIPSE, FORTIFY, FORTIFY ASSURA AND QUADRA ASSURA MP ICD	ST. JUDE MEDICAL	Modify the temperature range utilized for the temperature cycling of hybrid assemblies with organic substrates.
P910023/S420	10/18/2019	X - 30-Day Notice	ELLIPSE HYBRID	ST. JUDE MEDICAL	Alternate supplier for a telemetry coil component used on the Ellipse ICD hybrid.
P930014/S128	10/10/2019	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Implement new welding operating parameters with a modified welding method.
P930031/S066	10/07/2019	X - 30-Day Notice	WALLSTENT ENDOPROSTHEIS TIPS WITH UNISTEP PLUS	BOSTON SCIENTIFIC CORP.	Expansion of the manufacturing clean room.
P940019/S057	10/07/2019	X - 30-Day Notice	WALLSTENT RP ENDOPROSTHESIS ILIAC	BOSTON SCIENTIFIC SCIMED, INC.	Expansion of the manufacturing clean room.
P950022/S128	10/24/2019	X - 30-Day Notice	DURATA AND OPTISURE HV ACTIVE STEROID ELUTING CARDIAC LEADS	ST. JUDE MEDICAL, INC.	Update the in vitro elution methods for high voltage active fixation leads.

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P950037/S205	10/18/2019	X - 30-Day Notice	PULSE GENERATOR, PERMANENT IMPLANTABLE, PULSE-GENERATOR, PACEMAKER EXTERNAL, ADAPTER AND DRUG ELUTING PERMANENT RIGHT VENTRICULAR/RIGHT ATRIAL PACEMAKER ELECTRODES, STYLET, CATHETER AND BLIND PLUG ACCESSORY	BIOTRONIK, INC.	Replacement of the sterilization chamber corpus.
P960009/S359	10/13/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components.
P960009/S360	10/24/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update several manufacturing process changes for the XT097 and XT116 TAZ Series tantalum capacitors.
P960013/S109	10/24/2019	X - 30-Day Notice	TENDRIL, OPTISENSE	ST JUDE MEDICAL	Adjust the sterilization load configuration at the Abbott Penang Malaysia manufacturing facility.
P960016/S080	10/25/2019	X - 30-Day Notice	LIVEWIRE TC ABLATION, LIVEWIRE TC CABLES, SAFIRE ABLATION CATHETER AND SAFIRE CABLES	ST. JUDE MEDICAL	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.
P960030/S067	10/24/2019	X - 30-Day Notice	ISOFLEX	ST. JUDE MEDICAL	Adjust the sterilization load configuration at the Abbott Penang Malaysia manufacturing facility.
P960040/S443	10/29/2019	X - 30-Day Notice	IMPLANTABLE CARDOVERTER DEFIBRILLATOR (ICD)	BOSTON SCIENTIFIC	Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method.
P960042/S067	10/07/2019	X - 30-Day Notice	SLS/GLIDELIGHT	SPECTRANETICS CORP.	Change in supplier of an extruder outer jacket tubing component.
P960042/S068	10/21/2019	X - 30-Day Notice	SPECTRANETICS LASER SHEATHS SLS	SPECTRANETICS CORP.	Implement additional fiber production equipment.
P960058/S143	10/25/2019	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Change of manufacturing location for the RF Coil Manufacturing Process.
P970003/S227	10/24/2019	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Changes to the Surface Mount Technology Process for different generator models of the VNS Therapy Systems.

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P970004/S301	10/13/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components.
P970051/S192	10/08/2019	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM (EA22 STIFFENER)	COCHLEAR AMERICAS	Proposes the addition of a secondary supplier for the EA22 Stiffener.
P980016/S719	10/04/2019	X - 30-Day Notice	EVERA MRI DF1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR/VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI DR/VR ICD, VISIA AF MRI DF1/VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement new leak test stations and fixtures to be used for the CAPLEAKTEST process.
P980023/S095	10/18/2019	X - 30-Day Notice	PERMANENT DEFIBRILLATOR ELECTRODES, ACCESSORIES TO PERMANENT PACEMAKER ELECTRODE AND STYLEY CATHETER	BIOTRONIK, INC.	Replacement of the sterilization chamber corpus.
P980033/S056	10/07/2019	X - 30-Day Notice	WALLSTENT VENOUS RP & ENDOPROSTHESIS WITH UNISTEP PLUS	BOSTON SCIENTIFIC CORPORATION	Expansion of the manufacturing clean room.
P980040/S108	10/15/2019	X - 30-Day Notice	SENSAR 1-PIECE IOL, TECNIS 1-PIECE IOL, OPTIBLUE 1-PIECE IOL, ITEC PRELOADED DELIVERY SYSTEM, MULTIFOCAL 1-PIECE IOL, MULTIFOCAL 1-PIECE IOL, AND TORIC 1-PIECE IOL, TECNIS SYMFONY EXTENDED RANGE OF VISION, SYMFONY TORIC EXTENDED RANGE OF VISION OF IOL, AND SENSAR 3-PIECE MONOFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Consolidation of the cosmetic inspection step of the one-piece and three-piece intraocular lenses.

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P990080/S051	10/15/2019	X - 30-Day Notice	TECNIS 3-PIECE ACRYLIC MONOFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Consolidation of the cosmetic inspection step of the one-piece and three-piece intraocular lenses.
P000006/S053	10/25/2019	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS (IPP)	COLOPLAST CORP.	Change to add an additional laser marker to the manufacturing process.
P000039/S068	10/25/2019	X - 30-Day Notice	AMPLATZER SEPTAL OCCLUDER AND AMPLATZER MULTI-FENESTRATED SEPTAL OCCLUDER	ABBOTT MEDICAL	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.
P010012/S510	10/29/2019	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D)	BOSTON SCIENTIFIC CORP.	Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method.
P010013/S078	10/01/2019	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Replace a Stoll CMS 340 knitting machine with a Stoll CMS 822 knitting machine.
P010014/S094	10/09/2019	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Addition of a pneumatic-powered press in the post-casting forming process.
P010030/S126	10/21/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Implement a fixture to screen the fastener used in the LifeVest 4000 Electrode Belt.
P010031/S680	10/04/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S, XT CRT-D AND VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement new leak test stations and fixtures to be used for the CAPLEAKTEST process.
P020003/S009	10/25/2019	X - 30-Day Notice	TOROSA SALINE FILLED TESTICULAR PROSTHESIS	COLOPLAST CORP.	Change to add an additional laser marker to the manufacturing process.

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P020004/S170	10/08/2019	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Addition of an Oven Monitoring System to be used on ovens within the manufacturing processes for Excluder and Iliac Branch devices.
P020004/S171	10/24/2019	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Implementation of performance qualifications and updates to the sampling plan for the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER Iliac Branch Endoprosthesis.
P020012/S034	10/01/2019	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Implement a change on the Sampling and Monitoring plan for the USP Purified Water and Pure Steam WFI in the Suneva Medical facility at San Diego, California.
P020012/S035	10/25/2019	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Alternative Quality Control test method for PMMA microspheres.
P020024/S058	10/25/2019	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER, AMPLATZER DUCT OCCLUDER II AND AMPLATZER SEPTAL OCCLUDER	ABBOTT MEDICAL	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.
P020045/S090	10/09/2019	X - 30-Day Notice	FREEZOR CARDIAC CRYOABLATION SYSTEM	MEDTRONIC CRYOCATH LP	Modification of an inspection test specific to check valve (CV6) in the CryoConsole.
P030005/S190	10/29/2019	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY - PACEMAKER (CRT-P)	GUIDANT CORP.	Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method.
P030034/S015	10/08/2019	X - 30-Day Notice	CERVICALSTIM	ORTHOFIX, INC.	Modify the manufacturing process for sewing the garment assembly for the Orthofix SpinalStim Model 5212 and modify the manufacturing process to cut, split, and strip the ribbon cable for the Orthofix CervicalStim Model 5505 and Orthofix PhysioStim Models 53XX.
P030049/S013	10/25/2019	X - 30-Day Notice	ADVIA CENTAUR HBSAG	SIEMENS HEALTHCARE DIAGNOSTICS	Implement two additional tiers of standards identical to the approved standard used in manufacturing.
P030054/S371	10/15/2019	X - 30-Day Notice	QUADRA ASSURA, UNIFY, UNIFY ASSURA AND UNIFY QUADRA CRT-D	ST. JUDE MEDICAL	Modify the temperature range utilized for the temperature cycling of hybrid assemblies with organic substrates.
P040020/S092	10/10/2019	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implement new welding operating parameters with a modified welding method.
P040040/S038	10/25/2019	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.

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P040043/S113	10/31/2019	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS, GORE TAG CONFORMABLE THORACIC STENT GRAFT WITH ACTIVE CONTROL SYSTEM	W. L. GORE & ASSOCIATES, INC.	Use of an alternate coating on mandrels used as manufacturing aids.
P040044/S085	10/03/2019	X - 30-Day Notice	MYNXGRIP, MYNX ACE, AND MYNX CONTROL VASCULAR CLOSURE DEVICE (VCD)	ACCESS CLOSURE, INC.	Automate the hub sub-assembly process.
P050006/S080	10/31/2019	X - 30-Day Notice	GORE CARDIOFORM ASD OCCLUDER AND SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES, INC	Use of an alternate coating on mandrels used as manufacturing aids.
P050023/S136	10/18/2019	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (NON-CRT), DEFIBRILLATOR, IMPLANTABLE, DUAL CHAMBER, DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER, WITH CARDIAC RESYNCHRONIZATION (CT-D) AND STYLET, CATHETER	BIOTRONIK, INC.	Replacement of the sterilization chamber corpus.
P050028/S079	10/10/2019	X - 30-Day Notice	COBAS TAQMAN HBV TEST FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP, COBASTAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P050038/S033	10/04/2019	X - 30-Day Notice	ARISTA AH ABSORBABLE HEMOSTAT	C.R. BARD, INC.	Qualification of a new manufacturing equipment related to the drying, milling and sieving processes used to produce Arista AH Absorbable Hemostat.
P050047/S073	10/15/2019	X - 30-Day Notice	JUVÉDERM ULTRA, ULTRA XC, ULTRA PLUS, AND ULTRA PLUS XC	ALLERGAN	Implement a change in the manual cleaning procedure for equipment used in the manufacturing of Juvederm injectable gel products in the Pringy I building in France.

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P060030/S080	10/10/2019	X - 30-Day Notice	COBAS TAQMAN HCV TEST, V2.0, FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP, COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P060037/S062	10/24/2019	X - 30-Day Notice	NEXGEN LPS-FLEX/LPS-MOBILE BEARING KNEE	ZIMMER, INC.	Change in the density range of gamma sterilization from 0.09 to 0.2 g/cm ³ to 0.05 to 0.15 g/cm ³ . The density range is used in the gamma sterilization of NexGen® LPSFlex/LPS-Mobile Bearing Knee manufactured at Zimmer Orthopedics Manufacturing Limited (ZOML) Shannon Ireland facility.
P070004/S020	10/15/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Addition of an additional snap gauge data input tool used to collect and document shell thickness measurements in manufacturing Sientra OPUS Silicone Gel Breast Implants.
P070004/S021	10/29/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Standardizing the frequency of filtering and replacing isopropyl alcohol (IPA) in the manufacturing of Sientra® OPUS Silicone Gel Breast Implants.
P070004/S022	10/29/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Addition of a Variable Frequency Drive (VFD) to the Dipping Hood blower system used in the manufacturing of Sientra OPUS® Silicone Gel Breast Implants.
P070008/S108	10/18/2019	X - 30-Day Notice	PULSE GENERATOR, PACEMAKER IMPLANTBLE WITH CARDIAC RESYNCHRONIZATION (CRT-P) AND DRUG ELUTING PERMANENT LEFT VENTRICULAR (LV) PACEMAKER ELECTRODE	BIOTRONIK, INC.	Replacement of the sterilization chamber corpus.
P080006/S141	10/23/2019	X - 30-Day Notice	ATTAIN PERFORMA LEAD AND ATTAIN STABILITY QUAD MRI LEAD	MEDTRONIC INC.	Update the preventive maintenance process of the crimping process.
P080011/S099	10/09/2019	X - 30-Day Notice	BIOFINITY TORIC	COOPERVISIO N, INC.	Manufacture of the Biofinity Toric (comfilcon A) Soft (hydrophilic) Contact Lens on Biofinity Line 4 at the facility in Hamble, United Kingdom.
P080025/S196	10/13/2019	X - 30-Day Notice	INTERM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODU LATION	Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components.
P090015/S009	10/25/2019	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Add an additional Incoming Quality Control (IQC) test for a reagent.
P100010/S097	10/18/2019	X - 30-Day Notice	ARCTIC FRONT ADVANCE PRO AND ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Equipment and process changes for manufacturing the balloon assembly of the Arctic Front Advance and Arctic Front Advance Pro Cryoablation catheters.

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P100020/S050	10/10/2019	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P100021/S078	10/17/2019	X - 30-Day Notice	TALENT OCCLUDER WITH OCCLUDER DELIVERY SYSTEM	MEDTRONIC VASCULAR	Supplier change for a component of the delivery system.
P100040/S039	10/17/2019	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Supplier change for a component of the delivery system.
P100044/S044	10/08/2019	X - 30-Day Notice	PROPEL, PROPEL MINI AND PROPEL CONTOUR (PROPEL FAMILY) SINUS IMPLANTS	INTERSECT ENT	New packaging vision inspection system.
P100045/S040	10/29/2019	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Change the network analyzer used for in-process frequency validation.
P100047/S147	10/07/2019	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Updates to the manufacturing process for the blister sealer.
P100047/S148	10/18/2019	X - 30-Day Notice	HEARTWARE HVAD SYSTEM	MEDTRONIC	Modifications to the assembly process for the Apical Coring Tool.
P110010/S169	10/11/2019	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM AND PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the analytical chemistry method used for material acceptance testing.
P110016/S065	10/25/2019	X - 30-Day Notice	FLEXABILITY AND FLEXABILITY SE ABLATION CATHETER AND FLEXABILITY CABLES, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.
P110020/S034	10/10/2019	X - 30-Day Notice	COBAS BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110033/S050	10/15/2019	X - 30-Day Notice	JUVÉDERM VOLUMA, VOLLURE, VOLBELLA XC	ALLERGAN	Implement a change in the manual cleaning procedure for equipment used in the manufacturing of Juvederm injectable gel products in the Pringy I building in France.
P110035/S053	10/07/2019	X - 30-Day Notice	EPIC VASCULAR SELF EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Expansion of the manufacturing clean room.
P110037/S050	10/10/2019	X - 30-Day Notice	COBAS AMPLIPREP AND COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P110038/S024	10/30/2019	X - 30-Day Notice	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Change to the delivery system hydrophilic coating process and test specifications.
P110042/S128	10/10/2019	X - 30-Day Notice	EMBLEM S-ICD ELECTRODE	BOSTON SCIENTIFIC CORPORATION	Updates to inspection criteria for defects on the terminal boot of the EMBLEM S-ICD electrode.
P110042/S130	10/29/2019	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method.
P120019/S030	10/10/2019	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST V2	ROCHE	Implement an alternate spectrophotometer for in-process QC testing.
P120021/S013	10/25/2019	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.
P130009/S102	10/17/2019	X - 30-Day Notice	EDWARDS EXPANDABLE INTRODUCER SHEATH SET	EDWARDS LIFESCIENCE S, LLC.	Addition of a new cleanroom to perform borescope inspections.
P130009/S103	10/28/2019	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCE S, LLC.	Modifications to the final assembly cleanroom and the associated gowning room.
P130017/S033	10/18/2019	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	New testing method.
P130017/S034	10/08/2019	X - 30-Day Notice	COLOGAURD	EXACT SCIENCES CORPORATION	Changes to third-party supplier's manufacturing processes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130017/S035	10/24/2019	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Reagent manufacturing scale-up.
P130017/S036	10/22/2019	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Scale up manufacturing on 2 reagent components
P130021/S065	10/30/2019	X - 30-Day Notice	ENVEO R AND ENVEO PRO DELIVERY CATHETER SYSTEM OF THE COREVALVE	MEDTRONIC COREVALVE LLC	Introduce the option of using an additional autoclave.
P130021/S066	10/29/2019	X - 30-Day Notice	COREVALVE EVOLUT R AND EVOLUT PRO SYSTEMS	MEDTRONIC COREVALVE LLC	Addition of new equipment for the manufacturing of delivery catheter system sub-assemblies.
P130026/S052	10/25/2019	X - 30-Day Notice	TACTICATH QUARTZ CONTACT FORCE ABLATION CATHETER AND TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL	Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri.
P130028/S030	10/25/2019	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Addition of an alternate supplier of the silicone seals used to manufacture the header assembly of the Algovita Implantable Pulse Generators (IPGs).
P140003/S058	10/03/2019	X - 30-Day Notice	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, AND IMPELLA 5.0/LD SYSTEMS	ABIOMED, INC.	Add an alternative U.S. location for the rigid packaging supplier and minor modification to the rigid packaging material.
P140003/S061	10/30/2019	X - 30-Day Notice	IMPELLA 2.5 SYSTEM, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0 AND IMPELLA 5.5 WITH SMARTASSIST AND IMPELLA LD SYSTEMS	ABIOMED, INC.	Relocate the coil winding step in the cannula manufacturing process.
P140017/S017	10/30/2019	X - 30-Day Notice	EVOLUT R AND COREVALVE EVOLUT PRO SYSTEMS	MEDTRONIC INC.	Introduce the option of using an additional autoclave.

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P140023/S021	10/10/2019	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P140028/S044	10/11/2019	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Automate a process used to stretch delivery system tubing.
P140028/S046	10/07/2019	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Expansion of the manufacturing clean room.
P140031/S096	10/03/2019	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVES AND EDWARDS SAPIEN 3 ULTRA TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCE S, LLC.	Reduce the sampling plan from 100% to 4% LTPD for visual inspection of post-cleaned valve frames.
P140031/S097	10/17/2019	X - 30-Day Notice	EDWARDS ESHEATH INTRODUCER SET	EDWARDS LIFESCIENCE S, LLC.	Addition of a new cleanroom to perform borescope inspections.
P140031/S098	10/28/2019	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE AND EDWARD SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCE S, LLC.	Modifications to the final assembly cleanroom and the associated gowning room.
P140032/S042	10/24/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update several manufacturing process changes for the XT097 and XT116 TAZ Series tantalum capacitors.
P140033/S047	10/24/2019	X - 30-Day Notice	TENDRIL MRI	ST. JUDE MEDICAL, INC.	Adjust the sterilization load configuration at the Abbott Penang Malaysia manufacturing facility.
P150001/S075	10/30/2019	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Addition of a new curing process to increase production capacity of the MiniMed 630G Insulin Pump and the MiniMed670G Insulin Pump. The MiniMedi 630G Insulin pump is a component of the MiniMed 630G System with Smartguard. The MiniMed 670G Insulin Pump is a component of the MiniMed 670G System.
P150005/S048	10/07/2019	X - 30-Day Notice	INTELLATIP MIFI OPEN IRRIGATED	BOSTON SCIENTIFIC CORP.	Expansion of the manufacturing clean room.

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P150012/S084	10/29/2019	X - 30-Day Notice	MRI PACEMAKERS	BOSTONSCIENTIFIC	Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method.
P150014/S033	10/10/2019	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P150015/S035	10/10/2019	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P150036/S043	10/28/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE	EDWARDS LIFESCIENCE S, LLC.	Modifications to the final assembly cleanroom and the associated gowning room.
P150048/S038	10/10/2019	X - 30-Day Notice	EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCE S, LLC.	Transfer non-biological component manufacturing to the Singapore facility for the model 11500A valve.
P150048/S039	10/28/2019	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, INSPIRIS RESILIA AORTIC VALVE, AND EDWARDS PERICARDIAL MITRAL BIOPROSTHESIS	EDWARDS LIFESCIENCE S, LLC.	Modifications to the final assembly cleanroom and the associated gowning room.
P160017/S073	10/30/2019	X - 30-Day Notice	MINIMED 670G INSULIN SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a new curing process to increase production capacity of the MiniMed 630G Insulin Pump and the MiniMed670G Insulin Pump. The MiniMed 630G Insulin pump is a component of the MiniMed 630G System with Smartguard. The MiniMed 670G Insulin Pump is a component of the MiniMed 670G System.
P160035/S009	10/23/2019	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Add an inspection for the pump membrane thickness.
P160041/S026	10/10/2019	X - 30-Day Notice	COBAS CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an alternate spectrophotometer for in-process QC testing.
P170011/S016	10/03/2019	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Add an alternative U.S. location for the rigid packaging supplier and minor modification to the rigid packaging material.
P170011/S017	10/30/2019	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Relocate the coil winding step in the cannula manufacturing process.

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P170030/S004	10/25/2019	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Changes to the drug-substance manufacturing process.
P180011/S012	10/11/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the analytical chemistry method used for material acceptance testing.
P180011/S013	10/11/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Automate a process used to stretch delivery system tubing.
P180011/S016	10/07/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Expansion of the manufacturing clean room.
P180013/S001	10/30/2019	X - 30-Day Notice	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to the UV cure bonding step.
P180029/S013	10/07/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Expansion of the manufacturing clean room.
P180029/S014	10/03/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	New braid manufacturing equipment.
P180029/S015	10/13/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Transfer the inspection of the coiled spring pin component to an approved vendor.
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